This guide is prepared under EU funded TRTA II Programme which is implemented by UNIDO in association with ITC and WIPO

European Union

Government of Pakistan

United Nations Industrial Development Organization

International Trade Centre

WIPO

PAKISTAN GLOVES MANUFACTURERS & EXPORTERS

P G M E A

ASSOCIATION

CE MARKING

FOR PROTECTIVE GLOVES, MOTORCYCLE BOOTS AND OTHER PROTECTIVE CLOTHING

GUIDE FOR MANUFACTURERS

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Guide for Manufacturers

PREFACE

The European Union's “CE” regulatory conformity marking is crucial to all Pakistani manufacturers of personal protective clothing; without it, the very future of this major industry is called into question. Although it may seem burdensome and unnecessary, whether we like it or not, CE marking is compulsory for all protective clothing sold in Europe because Europe, with its population of about 500 million people, has to be one of, if not the most important market for Pakistani manufacturers. Therefore we either accept and adopt the CE marking, or allow this crucial market to be closed to us. Without access to the European market, however, it is difficult to imagine a successful future for Pakistani garment manufacturers.

Even for protective clothing not directly intended for the European market, the requirements of Europe, in terms of product performance and production system requirements (such as control of raw materials, in-production checks and assessment of finished products) can bring benefits to Pakistani manufacturers. These benefits, in particular, can be improvements in product quality, increased productivity and reduction of waste. While CE marking is only mandatory for products sold in Europe, it is recognized in many other countries where it can be used to provide a substantial marketing advantage.

This timely Guidance Document, funded by the European Union through the TRTA II project in Pakistan (managed by UNIDO in association with ITC and WIPO at Islamabad), provides an excellent presentation of the whole subject of CE marking. Its easy-to-read and clear style, combined with a presentation of all the stages which any manufacturer needs to go through in order to achieve CE marking, makes it an essential reading for any Pakistani manufacturer. It also provides example Technical Files, an essential component of the CE marking process, which can be copied by and adapted to the specific situation of any manufacturer. The development of the Technical File is one of the key stages in the whole process, and these examples make this stage a great deal easier.

Following the Guidance Document does not, of course, on its own guarantee that CE marking will be achieved; the products themselves need to be good enough to meet the performance required of them. This performance may, initially, be considered demanding and difficult to achieve but, by achieving it, our manufacturers can only stand to benefit.

The Guidance Document points the way to other areas where improvements can be made throughout the Pakistani garment industry, some of which have already been mentioned. Wider adoption of ISO 9001 quality management systems brings a discipline from which all manufacturers can benefit; improved productivity allows us to compete more effectively and efficiently, while higher product performance levels allow us to compete on quality rather than simply price. We need to take these improvements to heart if we are to have a healthy future for our industry.

This document too, surely, presents us as an industry with as many challenges as it does opportunities. Can we, for example, create a local testing capability so that we no longer have to rely on laboratories in Europe? Can we design products so that they meet the performance requirements the first time, every time? Can we improve raw material supplies so that axo dyes, now widely considered unacceptable, are no longer an issue? The choice seems clear: either we rise to and meet these challenges, in which case our industry will prosper, or we decline into relative obscurity, losing out to our better-prepared commercial rivals!

This Guidance Document is, therefore, highly recommended.

Muhammad Younis
Chairman
Pakistan Gloves Manufacturers and Exporters Association (PGMEA)

FOREWORD

There are many manufacturers of protective clothing, including work gloves and motorcycle boots, jackets, riding suits and gloves in Pakistan, based mainly but not uniquely in Sialkot, providing high levels of employment. Among these manufacturers are those that are producing good quality products, some of which are already being exported, others of which have the potential for export. For those manufacturers able to export, however, markets in the Middle East, Africa, Asia and, perhaps most importantly, in the European Union (EU), a market of some 500 million people, seem attractive.

A major reason preventing more manufacturers from exporting their products to the European Union is the regulatory requirements of Europe, which finds its evidence in the need for protective clothing to bear the “CE” conformity assessment marking. While some Pakistani manufacturers may currently be selling non-CE marked products in the EU, this illegal trade will not continue for long, and the manufacturers that do not start preparing for CE marking will find themselves losing their access to Europe.

The requirements, and the ways to meet them are, however, no different for manufacturers in Pakistan than for manufacturers in any other country of the world, including the EU itself. The market for protective clothing in Europe, in addition, is huge, maybe as much as €3 billion per year. If Pakistani manufacturers can improve their penetration into this market, the economic benefits could be substantial. Moreover, the 'discipline' imposed by CE marking may well help raise the overall safety and quality levels of Pakistani products.

It was to help Pakistani manufacturers meet the CE marking requirements that the EU funded Trade Related Technical Assistance (TRTA II) programme, implemented by the United Nations Industrial Development Organization (UNIDO) in partnership with the International Trade Centre (ITC) and the World Intellectual Property Organization (WIPO), started a CE marking programme in 2012. This programme aimed to develop a sustainable CE marking procedure, applicable by any Pakistani manufacturer, to test and validate this procedure by assisting some manufacturers to achieve CE marking, and to train and qualify a group of Master Trainers to assist other manufacturers.

At the end of this programme, in 2014, all of these aims have been met. The procedure for CE marking is what is presented in this Guidance. Three Pakistani glove manufacturers have achieved the marking for 11 different models in total following this procedure, and a small group of Master Trainers exists.

The efforts of the TRTA II CE marking programme team should be appreciated here, in particular Dr. Adam Pinney who, as an international CE marking expert, provided invaluable strategic and technical advice and who wrote this Guidance; Mr Badar ul Islam, who managed the programme on behalf of TRTA II; and Mr Qasar Wasique, TRTA II Sector Expert, who worked closely with the supported manufacturers.

We greatly acknowledge and appreciate the support of the European Union Delegation to Pakistan, and the assistance of PITAD, in developing this Guidance.

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United Nations Industrial Development Organisation (UNIDO)

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Chapter 1: INTRODUCTION

1.1) CE marking procedure

The CE conformity marking (and other regulatory compliance) is required by law for all protective clothing sold into the European Union, which means that products without the marking cannot be sold there. The CE marking is also required or recognized in other countries, such as the Middle East, North Africa, and some ex-Soviet republics. Obtaining the CE marking is, however, not an easy option. The technical standards required are high, the procedural aspects can be time-consuming, and the costs associated with testing and certification can also be relatively high. Attempts to obtain the CE marking should, therefore, be undertaken only by manufacturers who are serious about wanting it, who produce products of good quality, who possibly already operate a Quality Management system according to ISO 9001:2008, and who are willing to put in the necessary time and effort. For those manufacturers, therefore, this document explains the stages, and gives example documents, necessary to complete the process.

The stages towards CE marking are summarized below. Each stage is then discussed in more detail in the following chapters:

STAGE	DESCRIPTION
1) Identification of markets	CE marking represents a 'passport' for selling protective clothing into Europe and to other countries where it is recognized, but it does not guarantee that anyone will buy the product. Before making any attempt to obtain it, therefore, manufacturers must identify potential markets and verify that their products will meet market needs (Section 3.2)
2) Operation of factory production control	All manufacturers must operate a production control system to guarantee the conformity of their products. Although not compulsory, an ISO 9001:2008 system, certified by a reputable third party, is recommended (Section 3.3)
3) Selection of characteristics	Some characteristics are declared at the manufacturer's choice and, in principle, the manufacturer can choose the level of performance to declare for some characteristics. This is described in Section 3.4.
4) Preparation of documentation	Possibly the most important and time-consuming of the tasks. Manufacturers must prepare technical documentation which includes a description of the product(s), the production system, the production control system, the marking, labelling and user information, and how the product meets regulatory requirements (Section 3.5)
5) Submission of products for testing	All products to be CE marked require testing. This may involve testing by a notified test laboratory based in Europe and/or it may involve testing by an accredited test laboratory in Pakistan. If a Notified Body is involved, screening tests in Pakistan may help remove some non-conformities in advance (Sections 3.6.2 and 3.6.3)
6) Correction of defects	Screening tests and tests by a Notified Body may well show up defects and other non-conformities. Manufacturers must deal with these and re-submit products to the test laboratory until all of these are resolved (Section 3.6.4)
7) Drawing up of Declaration of Conformity (DOC)	On receipt of satisfactory reports from the test laboratory, the manufacturer must draw up a DOC as proof that his product meets all regulatory requirements. The DOC allows the manufacturer to affix the CE marking (Section 3.6.5)
8) Continuation of production / renewal of CE marking	The CE marking applies to a product defined by its design, its components, its production system and its production control system. Any changes to one or more of these, which may have an effect on the conformity of the product, may require re-testing or re-assessment (Section 3.6.6)

All manufacturers wishing to obtain the CE marking are strongly advised to inform themselves of the procedure and the requirements. This can be done by studying this document, by reading guidance on the internet, or by consulting with CE marking Expert Trainers through UNIDO.

While it is not the aim of this Guide to convince manufacturers of the benefits of CE marking, one of the glove manufacturers supported by the TRTA II project estimated that, as a result of obtaining the marking, their annual sales would increase by about 30 %, or a value of €450 000.

This document is written specifically for manufacturers of motorcycle boots, motorcycle gloves and other protective gloves. However, many of the principles and procedures apply equally to other protective clothing.

1.2) Regulatory background to the CE marking

The European Union (EU) is currently made up of 28 Member States, with a combined population of approximately 500 million people. The EU is a well-developed market, but one which has high levels of safety, consumer protection and quality as its basis. All Member States operate as part of a Single Market, which means that any product which has been shown to be safe in one place and at one time can be placed on the market of all Member States, without restriction and without any retesting or re-evaluation. This provision applies just as much to products entering the EU from third countries as it does to products made in Europe, as long as these products meet all EU requirements. The fact that a product is safe is usually demonstrated by it bearing the CE marking, which is why the CE marking represents the 'passport' which allows products to be sold in Europe.

'Safety' is a wide term which covers a number of different aspects. These include:

- absence of risk of personal injury (for clothing, this includes protection against mechanical actions and absence of sharp or protruding parts),
- performance in use (this includes tests such as dexterity),
- durability, including resistance to wear or repeated mechanical actions,
- absence of dangerous substances (certain substances, such as azo dyes and chromium VI are strictly limited in protective clothing), and
- correct choice of clothing and limits on use (protective clothing must be marked to ensure that users choose the right products for the likely risks).

The above requirements are mainly set out, in general terms, in the Personal Protective Equipment (PPE) Directive (89/686/EEC) which applies equally in all Member States. This means that all Member States have agreed on what is meant by a 'safe' product, so a product judged safe in one Member State is also judged safe in all other Member States. It also means that no Member State is allowed to impose additional requirements (such as additional safety levels or mandatory product certification) beyond those laid down in the directive.

Dangerous substances are covered by the Registration, Evaluation, Authorization and Restriction of Chemicals Directive (REACH, EC/1907/2006).

Manufacturers must comply with these two directives, and compliance with the PPE Directive leads to the product bearing the CE marking. There are, however, a number of choices and decisions to be made by manufacturers when applying the PPE Directive, and these are discussed in this Guide. The text of both directives can be found from the European Commission's web site on the internet, and it is strongly suggested that all manufacturers seeking CE marking read at least the PPE Directive.

Safety is generally expressed in performance, rather than prescriptive, terms, and manufacturers have the choice of how to satisfy the requirements. An example of a performance requirement (from the PPE Directive) is that “PPE must be so designed and manufactured that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest possible level”. Taking gloves as an example, the directive does not prescribe whether they should be made of leather or synthetic material, only that protection must be offered so that the user can do what he would normally do while wearing them.

The PPE Directive does not impose the satisfaction of all aspects of functionality, which means that for some characteristics, such as the slip and acid resistance of boots, the manufacturer can decide whether he wants to declare them or not. If he wishes to declare these optional characteristics, then the product must be tested

accordingly and meet the requirements. For all PPE, however, there are always some characteristics which must be satisfied, because these correspond to the minimum levels of protection which have to be satisfied for the clothing to be considered as 'protective'.

One crucial aspect of the PPE directive is that conformity to its requirements is always done under the direct responsibility of the manufacturer. This means, in particular, that the manufacturer is responsible for ensuring that every product he places on the market complies with the requirements of the directive and is properly CE marked; if a product is found to not comply (i.e. is unsafe), action will be taken against the manufacturer in the first instance.

For some types of clothing, the manufacturer is legally required to employ a notified third party (usually a body which issues an EC type approval certificate, see below). But this body does not authorize the affixing of the CE marking; it only provides information which assists the manufacturer in declaring that his products conform, which he does by using the CE marking.

In most cases for protective clothing, the general safety requirements are made more specific in harmonized European Standards, written in support of the PPE and REACH Directives. For gloves and motorcycle boots, the most relevant European Standards are:

- EN 388:2003, Protective gloves against mechanical risks,
- EN 420:2003+A1:2009, Protective gloves General requirements and test methods,
- EN 13594:2002, Protective gloves for professional motorcycle riders Requirements and test methods.*
- EN 13634:2011, Protective footwear for motorcycle riders Requirements and test methods.

* Although not yet published, this standard has been replaced by FprEN 13594:2014 and, although it is not yet widely available, this is the standard to be applied for motorcycle gloves.

In addition to responsibilities on manufacturers, EU provisions also impose obligations on importers and distributors. These must ensure that any products entering the EU market, or sold in that market, which are required to be CE marked, are CE marked and are accompanied by any necessary documentation. In short, they are committing an offence if they sell products without the CE marking when the products should indeed be marked. Manufacturers of protective clothing, therefore, need to be aware of this provision and refuse to supply protective products to any importer in the EU which does not impose CE marking.

It may be the case that some protective clothing is currently sold in Europe without the CE marking, partly because market surveillance authorities in Europe concentrate a lot of their efforts on more dangerous products and do not, therefore, have the resources to police the PPE market. This situation, however, is very likely to change in the next two or three years, after which any product without CE marking will no longer be allowed into Europe. A Pakistani manufacturer who does not have CE marking at this point will find that he loses his market in Europe and if he continues to supply non-CE marked products, both he and the importer could be guilty of an offence.

The various steps which manufacturers need to go through to obtain the CE marking are described in Chapter 3. Before that, Chapter 2 discusses the application of the PPE Directive, and also presents sources of information which are important in the CE marking procedure, so that manufacturers can understand what is expected of them and why, allowing them to understand the steps given in Chapter 3.

Chapter 2: THE APPLICATION OF THE PPE AND REACH DIRECTIVES

2.1) Introduction

This chapter explains in more detail what the PPE and REACH Directives require the manufacturer to do and how the manufacturer meets the directives' requirements. It also briefly covers market surveillance activities and what manufacturers may expect from them. While it is not crucial for manufacturers to understand all of the details of these directives, the more they understand, the better their position when discussing with importers, Notified Bodies and customers.

2.2) The Personal Protective Equipment(PPE) Directive - General Principles

The PPE Directive covers:

“personal protective equipment, hereinafter referred to as 'PPE' ... [where] for the purposes of this Directive, PPE shall mean any device or appliance designed to be worn or held by an individual for protection against one or more health and safety hazards.”

The words “designed ... for protection” are key here, because they have led to some manufacturers believing that they are not covered by the directive because their clothing is a 'fashion' item and, therefore, is not intended to provide protection. This belief could easily lead to manufacturers being subject to prosecution (especially in the event of accident or injury to a user of their products), because of two important principles:

1) if the manufacturer makes any claim that his product offers protection, then it is PPE in the meaning of the directive, and

2) if the user would reasonably believe that the product he buys is intended to offer protection, then again that product is PPE in the meaning of the directive.

As will be seen below, there can be a discussion, for clothing which provides very minimum protection, as to whether this clothing is PPE or not, typically the case for some gloves. In this case, the first principle above applies. For many other gloves, motorcycle boots and, for example, leather motorcycle riding suits, most purchasers would assume that these offer protection, and therefore the second principle above applies.

If a manufacturer is in doubt about whether his product is PPE, and therefore requires CE marking, he can search for similar products on the internet to see whether other manufacturers are applying it or not. The fact that many manufacturers might, collectively, be acting 'illegally' does not, however, provide any legal justification for Pakistani manufacturers to do the same. In practice, for very low risk products, the requirements for CE marking are not particularly demanding, the cost of obtaining it is low, and the benefits high (especially in markets where it is recognized but not obligatory); hence Pakistani manufacturers might as well save themselves from legal problems by obtaining it.

The PPE Directive covers three different 'categories' of product (the directive does not actually use the word 'category', but this is well accepted and widely used). Conventionally, these can be understood as:

- Category I = “simple design” (low-level protection),
- Category II = “neither simple nor complex design”,
- Category III = “complex design” (high-level protection).

Category I, simple design, PPE is equipment which protects the user against:

- mechanical action whose effects are superficial,
- cleaning materials of weak action and easily reversible effects,
- risks encountered in the handling of hot components which do not expose the user to a temperature exceeding 50°C, or to dangerous impacts,
- atmospheric agents of a neither exceptional nor extreme nature,
- minor impacts and vibrations etc. which do not affect vital areas of the body and whose effects cannot cause irreversible lesions, and
- sunlight.

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The following are examples of gloves which can be considered as Category I. According to the standard EN 420, they need to be marked “For minimum risks only”.

Category III, complex PPE, is equipment which protects against mortal danger, or against dangers that may seriously and irreversibly harm health. It covers only:

- filtering respiratory devices for protection against solid and liquid aerosols or irritant, dangerous, toxic or radio-toxic gases,
- respiratory protection devices providing full insulation from the atmosphere, including those for use in diving,
- PPE providing only limited protection against chemical attack or against ionising radiation,
- emergency equipment for use in high-temperature environments, the effects of which are comparable to those of an air temperature of 100°C or more, with possible presence of infra-red radiation, flames or the projection of large amounts of molten material,
- emergency equipment for use in low-temperature environments the effects of which are comparable to those of an air temperature of -50 °C or less,
- PPE to protect against falls from a height, and
- PPE against electrical risks and dangerous voltages or that used as insulation in high-tension work.

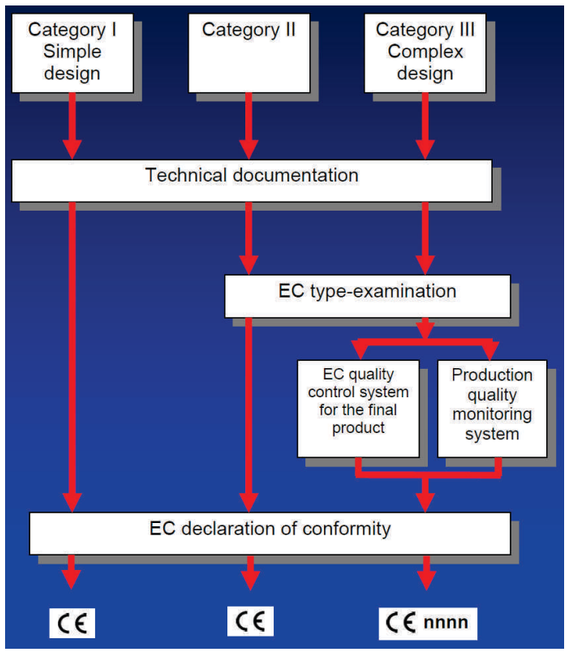
The following are products which would be considered as Category III:

Finally, Category II products are not actually defined or listed in the directive at all (even though they are perhaps the most important category). Whether a product is in Category II, therefore, depends on it, firstly, offering protection and, secondly, it not being in Category I or III. Motorcycle boots and gloves, and gloves which provide protection against cuts, penetration, abrasion, etc. all offer a level of protection higher than “mechanical action whose effects are superficial”, so they fall into Category II. The following are typical Category II products:

The rest of this Guide will concentrate mainly on Category II products, because this is the largest area of Pakistani manufacturing. Much of the advice given, however, would apply equally to the other two categories.

2.3) Attestation of conformity

The PPE Directive fixes three different systems of attestation of conformity (AoC), depending on the category of the clothing, i.e. the normal level of risk associated with the use of that clothing. AoC refers to 'who' is involved in demonstrating that the product meets the requirements of the directive. The manufacturer must apply the AoC system required for his category of clothing, which may need the intervention of a Notified Body based in Europe (Category II products). The different systems are shown below:



As can be seen from the figure above, all categories require the manufacturer to prepare technical documentation; this is covered in Chapter 3 of this Guide. The technical documentation has to include test results and, for Category I, these tests may be done by the manufacturer himself (if he has the necessary test equipment) or by any suitably competent third party laboratory of the manufacturer's choice.

Even for Category I products (lower-risk), manufacturers may need to involve a third party test laboratory, because it is highly unlikely that they will have all the test equipment required for the full range of tests (and will not have the equipment for testing dangerous substances). In this case, they may opt to use a Notified Body (defined below, competent to test Category II products) because this body will have the necessary test equipment. If the manufacturer uses a Notified Body for Category I products, however, the body is neither allowed to claim to be or act as a Notified Body nor allowed to issue a type-approval certificate.

Notified Bodies are product certification bodies or test laboratories which are recognized, by EU Member States, as being competent to assess products under the PPE Directive. These bodies have to be based in Europe (although they may have representatives in other countries such as Pakistan). Category II PPE requires the intervention of a Notified Body to perform the EC type-approval testing and this means, therefore that, to obtain a CE type approval certificate, test samples will need to be sent to Europe for testing.

Category III products (not really covered by this Guide) are assessed in the same way as Category II ones, except that, in addition to performing type approval testing, a Notified Body has to be involved in assessing the manufacturer's factory production control system (either a final product quality control system or a production monitoring system) and, in this case, the reference number of the body which assessed the system has to appear

with the CE marking (hence the “nnnn” in the picture above). The choice of a suitable Notified Body is discussed in Chapter 3 below.

2.4) Essential requirements of the PPE Directive

The PPE Directive sets out general safety and marking requirements which have to be met by all products, and then it also gives specific requirements which only need to be met by equipment having certain functions. The following table lists those essential requirements from the directive which are most likely to apply to gloves and boots:

Essential Requirement

1. General requirements PPE must provide adequate protection against all risks encountered.

2. Design principles

Ergonomics: PPE must be so designed and manufactured that, in the foreseeable conditions of use for which it is intended, the user can perform the risk-related activity normally whilst enjoying appropriate protection of the highest possible level.

3. Innocuousness of PPE

Absence of risks and other 'inherent' nuisance factors: PPE must be so designed and manufactured as to preclude risks and other nuisance factors under foreseeable conditions of use.

Suitable constituent materials: PPE materials and parts, including any of their decomposition products, must not adversely affect user hygiene or health.

Satisfactory surface condition of all PPE parts in contact with the user: Any PPE part in contact or in potential contact with the user when such equipment is worn must be free of roughness, sharp edges, projections and the like which could cause excessive irritation or injuries.

Maximum permissible user impediment: Any impediment caused by PPE to movements, postures to be adopted and sensory perception must be minimized; PPE must not cause movements which endanger the user or other persons.

4. Comfort and efficiency

Adaptation of PPE to user morphology: PPE must be so designed and manufactured as to facilitate correct positioning on the user and to remain in place for the foreseeable period of use, bearing in mind ambient factors, movements to be made and postures to be adopted. For this purpose, it must be possible to optimize PPE adaptation to user morphology by all appropriate means, such as adequate adjustment and attachment systems or the provision of an adequate size range.

Lightness and design strength: PPE must be as light as possible without prejudicing design strength and efficiency. Apart from the specific additional requirements which they must satisfy in order to provide adequate protection against the risks in question (see 3), PPE must be capable of withstanding the effects of ambient phenomena inherent under the foreseeable conditions of use.

5. Relevant information to be supplied

When PPE is placed on the market it must have all relevant information on:

(a) storage, use, cleaning, maintenance, servicing and disinfection. Cleaning, maintenance or disinfectant products recommended by manufacturers must have no adverse effect on PPE or users when applied in accordance with the relevant instructions;

(b) performance as recorded during technical tests to check the levels or classes of protection provided by the PPE in question;

(c) suitable PPE accessories and the characteristics of appropriate spare parts;

(d) the classes of protection appropriate to different levels of risk and the corresponding limits of use;

(e) the obsolescence deadline or period of obsolescence of PPE or certain of its components;

(f) the type of packaging suitable for transport.

6. Additional requirements

PPE incorporating adjustment systems: If PPE incorporates adjustment systems, the latter must be so designed and manufactured as not to become incorrectly adjusted without the user's knowledge under the foreseeable conditions of use.

PPE 'enclosing' the parts of the body to be protected: As far as possible, PPE 'enclosing' the parts of the body to be protected must be sufficiently ventilated to limit perspiration resulting from use; if this is not the case, it must if possible be equipped with devices which absorb perspiration.

PPE subject to ageing: If it is known that the design performances of new PPE may be significantly affected by ageing, the date of manufacture and/or, if possible, the date of obsolescence, must be indelibly inscribed on every PPE item.

PPE incorporating components which can be adjusted or removed by the user: Any PPE components which can be adjusted or removed by the user for the purpose of replacement must be so designed and manufactured as to facilitate adjustment, attachment and removal without tools.

PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety: The identification or recognition marks directly or indirectly relating to health and safety affixed to these types or classes of PPE must preferably take the form of harmonized pictograms or ideograms and must remain perfectly legible throughout the foreseeable useful life of the PPE. In addition, these marks must be complete, precise and comprehensible so as to prevent any misinterpretation; in particular, when such marks incorporate words or sentences, the latter must appear in the official language(s) of the Member State where the equipment is to be used

PPE in the form of clothing capable of signalling the user's presence visually: PPE in the form of clothing intended for foreseeable conditions of use in which the user's presence must be visibly and individually signalled must have one (or more) judiciously positioned means of or devices for emitting direct or reflected visible radiation of appropriate luminous intensity and photometric and colorimetric properties.

Impact caused by falling or projecting objects and collision of parts of the body with an obstacle: Suitable PPE for this type of risk must be sufficiently shock-absorbent to prevent injury resulting, in particular, from the crushing or penetration of the protected part, at least up to an impact-energy level above which the excessive dimensions or mass of the absorbing device would preclude effective use of the PPE for the foreseeable period of wear.

Prevention of falls due to slipping: The out soles for footwear designed to prevent slipping must be so designed, manufactured or equipped with added elements as to ensure satisfactory adhesion by grip and friction having regard to the nature or state of the surface.

Protection against (static) compression of part of the body: PPE designed to protect part of the body against (static) compressive stress must be sufficiently capable of attenuating its effects to prevent serious injury or chronic complaints.

Protection against physical injury (abrasion, perforation, cuts, bites):PPE constituent materials and other components designed to protect all or part of the body against superficial injury caused by machinery, such as abrasion, perforation, cuts or bites, must be so chosen or designed and incorporated as to ensure that these PPE classes provide sufficient resistance to abrasion, perforation and gashing under the foreseeable conditions of use.

Strictly speaking, to meet his legal obligations, the manufacturer needs to go through all the essential requirements listed in Annex II of the directive so as to identify exactly which ones apply to his product. However, in order to meet the requirements of the directive, the manufacturer has two main options:

1) he applies a harmonized European Standard which has been written in support of the PPE Directive and therefore which has already selected and 'expanded' the requirements and given them in terms of requirements and test methods which apply specifically to certain products; or

2) he complies directly with the requirements given in the directive, in which case he has to perform a risk assessment, identify for himself the requirements on his product, and propose suitable test or assessment methods to satisfy them.

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In reality, demonstrating conformity by applying a harmonized European Standard (where the word “harmonized” means “accepted by Member States as giving a presumption of conformity with the provisions of the directive”) is so much simpler than direct compliance that only the standards approach will be discussed in the rest of this Guide. By adopting a standard, the manufacturer can assume that its writers have already chosen which requirements of the directive apply, and therefore he need not, in general, do the selection himself.

For boots and gloves, the main harmonized European Standards were shown in Chapter 1. All harmonized standards which support the PPE Directive can be found on the internet, at:

http://ec.europa.eu/enterprise/policies/european-standards/harmonised-standards/personal-protective-equipment/index_en.htm

So the appropriate standard to use, while applying for CE marking for protective equipment other than gloves and boots, can be found on this website.

It is important that manufacturers check the website above to ensure that they are applying the most recent version of the standard(s), which is a legal obligation. In addition, if a standard is changed technically (and therefore the new version would be listed on the website), manufacturers have to apply the new version, and this may well require new testing.

2.5) The Reach Directive

In principle, the REACH Directive applies to every product placed on the EU market, and it has an extensive list (about 600 pages) of all the restricted or banned substances which cannot be used in products. The main dangerous substances likely to be present in protective clothing are azo dyes and Chromium VI, and the requirement to test for these are included in some standards. The manufacturer can rely on the Notified Body, however, for advice on whether any additional assessment needs to be done to satisfy REACH.

2.6) Identification and selection of a Notified Body

As already discussed, Category II (and Category III) PPE requires the intervention of a Notified Body to perform type approval testing and, for Category III, assessment of factory production control. Manufacturers of Category I products may also use a Notified Body to perform tests but, in this case, the body acts like a third party test laboratory, not a Notified Body. This Guide is unable to recommend any specific Notified Body or Bodies, but it does show how manufacturers can identify them and then gives some considerations for how to select them.

All Notified Bodies working under the PPE Directive are listed on the EU's NANDO website:

http://ec.europa.eu/enterprise/newapproach/nando/index.cfm?fuseaction=search.main

On entry to this web page, there is a 'Free search' screen as follows:

Free Search:

Keyword On Bodies:	
Keyword On Legislations:	
Keyword On Articles / Annexes:	
Keyword On Procedures:	
Keyword On Products:	
Keyword On Horizontal Technical Competence:	

Typing “Personal Protective Equipment” into “Keyword on Legislations” will produce the list of Notified Bodies competent to work under the PPE Directive. By clicking on the name of the body, its details can be found. The scope of competence of each body can then be known by clicking on the “HTML” or “PDF” tabs against the legislation, which will call up the accreditation scope of the body.

A manufacturer in Pakistan is entitled to use any of the bodies given in the NANDO list and, in principle, all bodies are equally technically competent and their results equally acceptable. However, a number of considerations may help in guiding manufacturers on how to choose a suitable body:

- although, in principle, all Notified Body are equally acceptable, manufacturers should check that the body they use will be accepted by their customers; this may mean choosing a well-known body with a good international reputation,
- ensure that the body is willing to provide only type approval certification (as required for CE marking), and is not suggesting full product certification or wants to assess the manufacturer's FPC system, which would be beyond the requirements of CE marking (this does not prevent manufacturers from seeking voluntary product certification, if they so wish),
- typical costs of testing and certification, per model (see below) are likely to be between €2 000 and €3 000 for gloves, and €1 500 to €4 000 for motorcycle boots. The cost per model will be proportionally higher if the manufacturer submits only one or two models but will be cheaper if he submits more models at the same time (see below),
- bodies which offer a price much below or much above the price ranges given above should be treated with some suspicion,
- a body which has a representative in Pakistan may make contact between the manufacturer and the body easier, but this is not essential,
- the body needs to be willing to work in English,
- there could be some economies if the manufacturer uses the same body for type-approval testing as for third party ISO 9001 system certification, if the manufacturer opts for this,
- the turn-around time will typically be quoted as 4-6 weeks, but this does not automatically mean that results will be received within 6 weeks of the laboratory receiving the samples; this time is often the total time taken to perform the tests, and manufacturers should seek, from bodies, agreement on starting and finishing times,
- although difficult to judge, the cost of any retesting (in the event of failure) should be discussed, and
- the length of validity of the type-approval certificate, and the cost of renewing this, is a factor*.

* As long as nothing changes, with the product, its design, materials, etc., the production method, the production control method or the harmonised standard(s), no retesting or repeat testing is necessary for CE marking purposes. The body may require that the type-approval certificate is renewed from time to time (every 3 to 5 years is typical), but this renewal is intended mainly to ensure that nothing has changed. This renewal is, therefore, an administrative rather than a technical exercise, and should not be expensive (maybe €200 - €300). Manufacturers should be cautious of bodies requesting renewal of the certificate more frequently than this and/or are charging substantially more.

Beyond these considerations, it is suggested that manufacturers identify a number of possible Notified Bodies, send the draft Technical File to each of them, and then make a selection based on the offers received. Lowest cost should not necessarily be used as the only criterion on which the decision is made.

Two questions which are often asked are:

1) can manufacturers use test laboratories in Pakistan in support of CE marking, and

2) does the manufacturer need an Authorised Representative based in the EU?

The need to use a Notified Body for Category II PPE has been discussed above and, currently, Notified Bodies cannot exist in Pakistan. A manufacturer is entitled, though, to use a laboratory in Pakistan to test Category I products (where no Notified Body is required) and may also use a national laboratory to undertake both screening tests (prior to CE marking, see Chapter 3 below) and to perform testing in support of FPC (if any such tests are required).

The only other way in which a Pakistani test lab could undertake CE marking tests is by entering into an agreement with an EU-based Notified Body. Then, by sub-contract, the Notified Body would authorize the Pakistani test lab to perform tests on its behalf. For this to happen, however, the Pakistani test laboratory would need to be performing at a very high level of competence; no such arrangements exist at present.

The Authorised Representative (AR, a term which appears in many directives) is an organization, based somewhere in the EU, which is contracted by the manufacturer to perform certain tasks on the manufacturer's behalf. The AR may, for example, hold the Declaration of Conformity and Technical File on the manufacturer's behalf, and act as the contact point for market surveillance authorities. The AR may also manage the work of the Notified Body, but is not permitted to take on any of the responsibilities placed on the manufacturer.

Pakistani manufacturers have no obligation to appoint an AR, and there seems to be little benefit in them having one. The AR may also act as the importer, in which case he takes on the responsibilities of an importer, as described above.

2.7) Market surveillance

The CE marking of a product shows that, in the European Union at least, it is given a presumption of conformity with all applicable regulatory requirements, which means that the letters indicate that the product has already been tested and shown to be safe. As a matter of principle, therefore, a manufacturer which has followed all the steps in this Guide and has applied the CE marking correctly, should not be subject to any market surveillance (which includes customs) actions. Nonetheless, because the control of PPE may well be tightened over the next few years, this section describes briefly the possible actions, and how manufacturers should respond.

Market surveillance authorities have three main ways of checking whether a product is legally placed on the European market:

- checking the presence of the CE marking symbol, and that technical information and user instructions are present and credible. A lack of CE marking, on a product which should bear it, or a lack of technical information or user instructions, is itself an offence, whether the product is safe or not;
- documentary checks, where the authorities ask to see proof of conformity via the Technical File. If a manufacturer does not hold a TF, if the file is incomplete (does not contain test results, for example) or the manufacturer refuses to send the TF to the authorities, this is also an offence; and
- visual assessment and/or product tests. Authorities will easily spot obvious faults and, in such cases, they may conduct testing.

The simplest ways in which manufacturers can avoid market surveillance actions are by, firstly, keeping their Technical File fully up to date and correct, which includes ensuring that certificates are up to date and that any new test reports are also included. Secondly, by verifying every product or batch of products they supply, including its marking and accompanying information, and by being very careful of making any changes to the product, its design or its component parts without informing the Notified Body of this.

In the unlikely event that market surveillance action is taken, the importer and/or the manufacturer will receive a notice explaining the reasons for the action, what needs to be done to correct it and the time allowed for this. In such cases, the required actions must be taken, and the authorities informed, or there is a risk that the product will be suspended or removed from the market.

2.8) Further information

There is a great deal of information related to EU regulations, directives and CE marking on the internet, and it is recommended that manufacturers consult this from time to time so as to better understand the process and requirements. Perhaps the best source is what is known as the Blue Guide 2014, which gives a good and thorough presentation of the subject and can be found at:

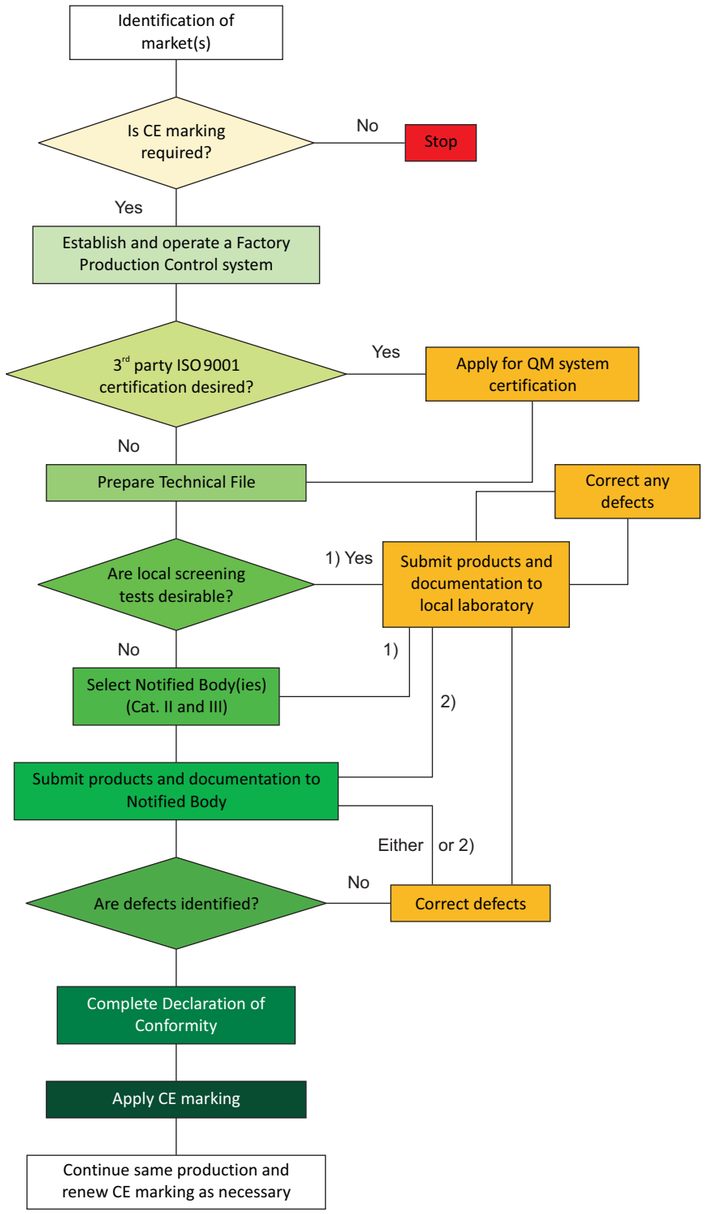
http://ec.europa.eu/enterprise/policies/single-market-goods/documents/internal-market-for-products/new-legislative-framework/index_en.htm

Other guidance can be found simply by typing the name of a directive into a search engine, but different levels of information need to be treated differently. The European Commission's web site (anything starting with ec.europa.eu) can be considered to be definitive and correct, but will often lack the technical details required by manufacturers. At a second level, many Notified Bodies provide information through their websites (often in the form of a flowchart or guidance document for CE marking) and these sites can also be considered to be accurate. At a third level, websites of manufacturer’s associations and other organizations may provide useful information, but the accuracy of the information they provide may need to be verified.

Chapter 3: STAGES TO BE FOLLOWED FOR CE MARKING

3.1) Presentation of stages

The stages towards CE marking for Category II products, as shown in the Introduction, are given in the following flowchart. Each stage is then described in detail in the following sections of this chapter, although some of the stages shown in this figure are combined in the explanation sections.



3.2) Identification of markets

There is very little point in making any preparations for CE marking (apart, perhaps, from seeking a third party certified Quality Management System according to ISO 9001, which has benefits independent of CE marking), unless the manufacturer first identifies that there is a market for his products in Europe or in other countries. Having identified such markets, the manufacturer then needs to decide whether CE marking is mandatory from a regulatory point of view (the case for European Union and EFTA countries), whether it is required by or advisable for the market (Middle East, some north African countries), whether it brings a marketing advantage even if not required (for example ex-Yugoslavian and ex-Soviet countries), or whether it is not necessary at all. This section is not a guide on how to identify potential markets, but it does give some guidelines which might prove helpful.

While the CE marking allows products to demonstrate that they are legally entitled to be placed on the market (and is, therefore, a marking primarily intended for customs and market surveillance authorities), it does not indicate that customer requirements will be satisfied. Customer requirements often go beyond the requirements of CE marking, and cover aspects such as price, functionality, appearance, durability (although some CE marking tests also cover durability), manufacturer's reputation and after-sales service; all of these aspects should be considered by manufacturers before starting the CE marking process.

Two aspects of meeting customer demand are the selection of which of the optional characteristics to assess and declare (this is particularly relevant for motorcycle gloves and boots), and what level of performance is required (especially for gloves). How this is represented in standards, and how the manufacturer may arrive at a choice, is discussed below.

There is an initial cost associated with obtaining the CE marking (mainly covering type approval testing and certification, and the cost of purchasing standards). Typically, this cost will be in the broad range of €2000 to €3000 for gloves and €5000 to €10000 for boots, depending on how many models are considered at the same time. This should add very little to the unit cost for any product sold in large or normal quantities; hence cost should not generally be a factor in deciding whether to obtain CE marking or not.

Manufacturers should also take into account the time required to obtain the CE marking. This is likely to be 6 months minimum (even while assuming that everything proceeds smoothly and no re-design or re-testing of the product is necessary) and could easily be longer. Manufacturers should not, therefore, undertake to supply CE marked products until they are certain that they will be able to.

Manufacturers should also be aware that CE marking requirements can be technically demanding, especially with regard to user safety and avoidance of hazardous substances content. Products which can be sold in Pakistan, for example, may require redesign to be suitable for use in the EU, and the difficulties associated with this re-design, together with the time necessary to implement it, should be considered before opting for CE marking.

In summary, although CE marking is necessary to access or maintain EU markets, and the costs involved are easily outweighed by the financial benefits, it is not something which should be considered lightly. It should only be considered by manufacturers who believe that their products are capable of meeting the requirements for CE marking, who have identified that a market exists for their products in countries where CE marking is either mandatory or required by the market, and who are serious about supplying these markets. Finally, it is only something to be considered by those manufacturers willing to put in the resources and effort required to achieve it!

3.3) Operation of factory production control

The PPE Directive requires that manufacturers must operate some sort of factory production control (FPC) system. However, this is not the same as a Quality Management system (but see below). CE marking should not be confused with normal third party product certification, where the certification body will test products in order to issue a certificate in the first place, but will then, from time to time, test further samples to ensure continued compliance, and where the product certificate may be suspended or withdrawn if the product no longer complies. For CE marking, the product needs to be initially tested in order to demonstrate conformity (and, as explained above, this is done by a Notified Body based in the EU for Category II or III products) but, after this initial testing, there is no repeat or routine further testing (as a condition of CE marking).

The primary purpose of FPC, therefore, is to ensure that all future products manufactured remain the same as those submitted for type approval; this will ensure that the results of the type approval tests remain valid for all future products. To illustrate this, the PPE Directive requires that:

- "The manufacturer shall verify that the manufacturing process, including the final inspection of PPE and

tests, ensures the homogeneity of production and the conformity of PPE with the type described in the EC type-approval certificate".

As long as the primary objective, that of ensuring the production of conforming products for which the type approval test results remain valid, is met, there are no other, more specific, requirements or definitions on FPC. In practice, an FPC system will be made up of incoming material and component checks, in-process tests and controls, finished product testing, and packaging/shipment controls, but the types and frequencies of these tests and controls are left to each individual manufacturer's discretion.

There is no direct third party control of FPC as a requirement for CE marking, except for Category III products. The FPC system has to be described, in appropriate detail, in the Technical File (see the examples in Annexes 1 and 2), to allow checking whether what is described is credible and adequate. The directive also requires manufacturers to hold FPC records (for 10 years). What this means, therefore, is that the obligation to control production appropriately falls entirely on the manufacturer. Importantly, if any non-conformities with the product are detected, or an accident or injury is caused as a result of the product, and the manufacturer could not produce results to demonstrate that FPC had been applied correctly, he may well have committed an offence.

The PPE Directive does not make the use of a certified ISO 9001 Quality Management system mandatory. It is accepted, though, that if manufacturers have such a certified system, which has been assessed by a duly accredited certification body, then they will be considered to have met the regulatory requirements for FPC. Manufacturers should, therefore, consider attaining ISO 9001 certification, not only for CE marking purposes but also as a benefit in its own right.

If a manufacturer uses ISO 9001 certification as the basis on which he claims satisfactory FPC, a copy of his certificate (which must be current) has to be given in the Technical File. Even in this case, he must still describe the main stages of his control system.

Strictly speaking, a manufacturer does not need to have a functioning FPC system before he submits his products for type approval testing. Because it can take time (typically 6 months to a year) to implement such a system, however, it is recommended that this system is operational before type approval testing starts.

3.4) Selection of characteristics and performance levels

Various standards under the PPE directive identify some characteristics which are obligatory and must always be satisfied, while other characteristics are optional and the manufacturer may decide whether to assess and declare them, or not. Annex ZA of the standard (which identifies the full list of characteristics) does not distinguish between mandatory and optional, so the text of the standard needs to be read together with Annex ZA.

The standard for motorcycle boots, EN 13634, will be used to illustrate this principle. The table of characteristics and requirements in Annex ZA is shown below:

EU Directive 89/686/EEC, Annex II		Clauses of this European Standard
1.1.1	Ergonomics	4.8 and Annex A
1.1.2.1	Highest levels of protection	4.8 and Annex A
1.2.1	Absence of risks and other 'inherent' nuisance factors	Annex A
1.2.1.1	Suitable constituent materials	4.4.1, 4.4.2, 4.4.3, 4.5.4, 4.5.5, 4.5.6, 4.6.4 and 4.6.5
1.2.1.2	Satisfactory surface conditions of all PPE parts in contact with the user	4.8 and Annex A
1.2.1.3	Maximum permissible user impediment	Annex A
1.3.1	Comfort and efficiency	4.8 and Annex A
1.3.2	Lightness and design strength	4.5.2, 4.5.3, 4.6.3, 4.7.2, 4.7.3, 4.7.4, 5.2 and 5.3
1.4	Information supplied by the manufacturer	8
2.2	PPE 'enclosing' the parts of the body to be protected	5.5
2.4	PPE subject to ageing	8
2.12	PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety	7 and 9
3.1.2.1	Prevention of falls due to slipping	5.4
3.1.1	Protection against mechanical impact	4.4.4, 4.4.5 and 5.1
3.2	Protection against (static) compression of the body	4.9
3.3	Protection against physical injury (abrasion, perforation, cuts, bites)	4.7.2

The characteristics of this table which are optional are those shown highlighted in yellow (all other requirements must be met). These are:

5.1: Impact protection to the shin and ankle

5.2: Resistance to water penetration

5.3: Resistance to fuel oil of out-sole

5.4: Slip resistance of out-sole

5.5: Permeable uppers

Although it is the manufacturer's choice as to whether to declare these, slip resistance in particular is considered to be important and should be satisfied if possible, while resistance to water penetration might be considered desirable, especially for sale in the United Kingdom. As the market in Europe becomes more knowledgeable and customers start asking for better performance, the need to declare these characteristics may increase; at the moment, a manufacturer declaring more characteristics may have a marketing advantage over manufacturers which do not. One option open to the manufacturer is to ask the Notified Body to test all characteristics, including the voluntary ones (the cost of this is not particularly high), and then to declare those characteristics with positive results.

Not all of the requirements of this table require testing. Clauses 7, 8 and 9 of the standard cover marking, user information and pictograms. There is not, for example, any test for ageing of boots, but the manufacturer is required to suggest the lifetime of the boots in the user information.

This table can be compared with the table of characteristics taken directly from the directive as given in Section 2.4 above, and it can be seen that Annex ZA covers all of these, with one possible exception. One PPE requirement is PPE in the form of clothing capable of signalling the user's presence visually; this characteristic is not covered by Annex ZA or by the standard. What this means is that if the boots (or gloves, because the same situation applies for them) were to include reflectors or other visibility aids, the requirement of the directive would need to be complied with directly, rather than by using the standard.

For normal protective gloves, two of the proposed characteristics are optional: resistance to water penetration and electrostatic properties; while for motorcycle gloves, impact energy attenuation (knuckle protection) is also optional.

Some of the characteristics in PPE standards lead to possible different levels of performance. FprEN 13594 for motorcycle gloves and EN 13634 both have two basic levels of performance, 1 and 2, depending on the design and performance; while EN 380, for gloves providing mechanical protection, has four or five different levels, as the following table shows:

Test	Level 1	Level 2	Level 3	Level 4	Level 5
Abrasion resistance (number of cycles)	100	500	2 000	8 000	–
Blade cut resistance (index)	1.2	2.5	5.0	10.0	20.0
Tear resistance (N)	10	25	50	75	–
Puncture resistance (N)	20	60	100	150	–

Manufacturers cannot change the inherent performance levels of their products, because this is a direct result of the product design and materials used. But they can change design and/or materials to ensure that their products meet the levels required by their customers. If a product fails to meet Level 1, it needs to be marked "0", but it may also be marked "X" to show that the characteristic has not been tested.

3.5) Preparation of documentation

3.5.1) Introduction

Although this section covers mainly the preparation of the Technical File (TF) required to fully identify the product, there are in fact a number of decisions and actions that need to be taken in order to prepare this file. When EU directives talk about a "product", the "product" in question is actually defined not only by the physical item to be

tested, but also by the materials and components from which it is made, its manufacturing process, its factory production control system, its marking and labelling, the harmonized standard applied and even, in some cases, by who manufacturers it. Because the TF is required to uniquely identify the “product” which is CE marked, all of the information which goes to define it needs to be included in the TF. The various sub-sections in this section cover how the TF should be prepared, and Annexes 1 and 2 give examples which can be used as the basis for a manufacturer to prepare his own.

The Technical File serves quite a number of purposes, beyond just the needs of CE marking:

1) it is the complete definition of the “product” as discussed above, serving as a reference for the manufacturer as part of any Quality Management system,

2) it is the main document which satisfies the regulatory obligations on the manufacturer by describing how he has met the provisions of all applicable directives,

3) it can prove to market surveillance authorities that the product conforms because, if they question the conformity, they will usually ask to see the Technical File first,

4) it permits the manufacturer to show which characteristics (of the optional ones) he wants to be assessed, and what level of performance he wishes to achieve. Showing these, and other information which needs to be confirmed later in the process, in green is a helpful concept, because it guides the Notified Body in what needs to be tested. Once information is known, information in green is changed to black to confirm it,

5) it allows the manufacturer to obtain an outline quotation from candidate Notified Bodies before test samples are sent,

6) it permits the Notified Body to verify that the samples received for testing are really those which the manufacturer intends to produce, by checking that the samples delivered are the same as those described in the TF, and

7) it may be used, in full or in part, by the manufacturer as a 'sales brochure' for purchasers, importers, etc.

For these reasons, the TF is a crucial document, and its preparation needs to be as complete and accurate as possible. If the product samples sent to the Notified Body for testing do not fully correspond to what is described in the TF, the body will most likely reject them and not start testing, causing delay. For these reasons, manufacturers might consider getting external expert advice in the preparation of their file. If nothing else, it is worth checking the English (grammar and spelling), because poor English gives a poor initial impression as far as the Notified Body is concerned (in the same way that poor language in the user instructions gives a bad impression to purchasers).

Before reading the sections which follow, manufacturers should read earlier chapters of this Guide so that they fully understand the reasons for the TF and its contents. When and if following the model TF given in Annexes 1 or 2, manufacturers must ensure that all sections of the file are made specific to their products and their production systems.

3.5.2) Identification of the manufacturer(s)

In EU legislation, the 'manufacturer' is defined as the person responsible for affixing the CE marking, and whose name appears on or with the product. In most cases, the manufacturer will be the company which makes the product, and consequently it is the details of this company which appear at the beginning of the TF. However, in some cases the product may be sold entirely in someone else's name, in which case, from a legal point of view, it is that 'someone else' who becomes the 'manufacturer' of the product and acquires, as a consequence, all the responsibilities imposed on the manufacturer, which includes the need to hold a Technical File in his own name. The second 'manufacturer' may be the company which makes the product but sell sit under a different name.

It is beyond the scope of this Guide to go into details of the different responsibilities if the same product, made by one company, is sold by two or more different legal entities, and advice should be sought if this situation arises. If the same product is sold under two different names, both of which are trade names of the manufacturer who takes responsibility for the CE marking, then the TF needs to make clear that both names will be used to sell it.

If the product is to be distributed in someone else's names (i.e. the name of the distributor), without the distributor taking any responsibility for CE marking, then a distinction should be made between the manufacturer (with responsibility for CE marking) and the distributor, on the product, its packaging or the commercial documents. This could be done by the mention of “Manufactured by: ...” and “Distributed by ...”.

3.5.3) Identification of the product(s)

There are no strict rules on how many or how few products can be included in the same Technical File, so common sense and one important principle can be applied. If products from the same manufacturer are significantly different (their materials are different, their production system is different, etc.) so that there would basically be at least two separate sets of information in most sections of the TF, then it is probably better to prepare two or more separate documents.

The important principle, however, for type approval testing is that it is possible to 'group' similar products or models together, in what are called “variants”, in order to reduce the number of tests that need to be done. Grouping is actually done on the basis of a performance requirement, which can be expressed as follows:

Products may be grouped together into variants whenever it is clear that the results of testing any one product within the group are applicable to all other products within the same group. Products may be grouped differently depending on the characteristics being considered.

In addition, EC guidance on the PPE states:

“A product is considered as a variant of a “model” only if it differs in ways which have no influence on the expected protective properties. The Notified Body shall evaluate if a product can be considered as a variant. Size can usually be considered as a variant.”

This can perhaps best be explained by giving two examples. Firstly, if a manufacturer makes boot models using the same sole and sole-upper connection, the boots are variants as far as abrasion resistance of the sole and sole-upper bond strength are concerned, and these characteristics would be tested only once on one model. Other tests would possibly need to be done if other aspects of the boot design were different, but it would probably be sensible to group all such models into a single Technical File.

Secondly, if a manufacturer makes gloves using the same materials but different designs (different seams and seam patterns), the gloves would be variants in respect of material properties (pH, azo dyes, Chromium VI, cut resistance, etc.), but separate tests on each model would need to be done for, for instance, seam strength.

There are significant cost savings to be achieved by using variants. As a typical example, the cost of testing and certifying one pair of boots may be €5 000, while the total cost for six variants is just €6 000, i.e. €1 000 per model instead of €5 000. Manufacturers may propose variants in their Technical File, but the Notified Body needs to accept these, and this may only be possible once the body has been selected and test samples have been received. Once variants are accepted, the test reports and type approval certificate need to state not only which model(s) were tested but also for which other models the results remain valid. In this way, it is clear that all models proposed by the manufacturer have been approved.

As already stated above, the TF must contain a complete and accurate list of all the component parts, including materials, used to make up the product. The specification of each component part needs to be given in sufficient detail for it to be properly and uniquely identified, and this may include, for example, the material, any reference number or identifier, the technical specification (in brief) and the name and address of the supplier. The supplier information is important because if the supplier is changed, even if the specification of the component part appears to be the same, one or more of the test results could be invalidated. The examples in Annexes 1 and 2 show appropriate levels of detail.

One or more photographs of the products may be helpful, but this is not a requirement.

3.5.4) Description of the production method and factory production control system

It is necessary to describe both the production method and the FPC system in enough detail that they can be understood and that the adequacy of the FPC system can be judged. They do not, though, need to be described in full detail, and an outline flowchart is often sufficient. The level of detail given in the example TFs in Annexes 1 and 2 is appropriate but, if in any doubt, it is better to give too much detail rather than too little. All key stages related to production and production control should be shown including, for example, ordering and reception of materials and component parts, and packing, labelling and dispatch, because both of these have a bearing on the conformity of products. Stages unrelated to production and production control, such as handling of customer orders or complaints, do not need to be given; it is best not to identify, by name, the people responsible for different stages because if one person leaves the TF would need to be changed (the function, however, e.g. “Production control supervisor” may be identified).

Even if third party ISO 9001 certification is used as partial proof of the adequacy of FPC (in which case a copy of a valid certificate has to be included in the TF), the key stages of the FPC system still need to be listed and/or described. This helps to ensure, should there be any doubt, that the third party certification is both genuine and adequate.

3.5.5) User information

The PPE Directive requires that adequate user information be given to allow the product to be correctly selected and used, to place any limitations on the use of the product, and to give maintenance advice where appropriate. Because of liability laws, especially in the EU, any restrictions on the use of the product (such as that the product must not be used if damaged) need to be given in the user information, because the manufacturer is then not responsible if the product is used in conditions outside of his specifications and an accident or injury occurs.

If the manufacturer already has user instructions (perhaps in the form of a User Manual), these may be copied directly into the TF (provided that they are in a language [usually English] which can be understood by the Notified Body). If at the time the TF is being prepared a User Manual does not yet exist and the text is, therefore, written for the first time in the file, when the User Manual or user instructions are printed, the text needs to be the same as that given in the TF, because the Notified Body will have assessed its adequacy.

There are no minimum or maximum specifications on the length or content of the user information, but the examples given in Annexes 1 and 2 are both typical and sufficient. Although unrelated to conformity, as stated above spelling and grammatical errors should be eliminated from the user instructions because, otherwise, this gives a bad impression to anyone reading those instructions.

3.5.6) Compliance with regulatory requirements, i.e. the PPE and REACH Directives

It is the manufacturer's responsibility to identify all of the regulatory requirements (i.e. directives) with which he must comply in order for his product to be legally placed on the market. Ignorance of the existence of a regulatory requirement would not be accepted, in the EU, as justification for the manufacturer not applying it.At the moment (2014), the regulatory requirements on protective clothing appear to be stable and unlikely to change immediately. But to give just one example of how requirements can change, currently motorcycle gloves are being tested to FprEN 13594:2014; as soon as this standard is published (likely in 2015), testing will be made to the new EN version of the standard.

This section of the TF needs to list the two directives which apply to the product, and to show how the manufacturer complies with them. When (as is assumed, in this Guide, to be the case) conformity is based on the application of harmonized European Standards, these standards need to be listed here, and the relevant requirements of the PPE Directive should also be listed.

The name and address of the body used to perform the type approval appears in this section. When the first draft of the Technical File is being prepared and the name of the body is not known, this information should be left blank or given in green; but once the body is known, the relevant information can be included.

3.5.7) Product marking

There are three locations where information regarding performance and CE marking may appear: on the product itself (usually on a label and/or moulded onto the sole of a boot), on the packaging and on accompanying documentation (which is usually the User Manual). This section of the Technical File indicates, by way of descriptions and examples, what information appears in which location.

To know what needs to be marked, the manufacturer has to read the relevant standard(s) which have been applied and follow the prescriptions given there. The examples shown in Annexes 1 and 2 come from the standards for protective gloves and motorcycle boots, but manufacturers need to change these examples to make them specific to their own products.

As with the user information discussed above, the example label and information to be given on the packaging and/or User Manual, and which appears in the Technical File, must be the same as what appears on and with the product.

There is no need to provide any specific information in relation to pH or REACH. The CE marking symbol itself shows that the product has met these requirements.

3.5.8) Test reports and certificates

These two final sections of the Technical File have to contain copies of all test reports and the type approval certificate received from the Notified Body. Once the Technical File is complete, with test reports and certificate included, and the Declaration of Conformity is signed and dated, the complete File should be sent once again to the Notified Body for final verification.

3.5.9) The Declaration of Conformity

The PPE Directive requires that the manufacturer prepares and then signs a Declaration of Conformity (DOC) and that a copy of this appears in the Technical File. The DOC is the statement, given by the manufacturer, acknowledging that he has ensured under his own responsibility that the products he sells conform to all applicable regulatory requirements. There is no definitive model for the DOC to follow, but that given in Annexes 1 and 2 is adequate.

At the time that the TF is first prepared, the DOC cannot be signed, because this can only happen when test results and a type approval certificate have been received. As soon as these are received, however, the DOC needs to be signed and a copy included in the TF.

The DOC also needs to be kept up to date. So, for example, if the harmonized standard changes and the product is retested, a new DOC will need to be prepared and signed.

3.6) EC type approval stages

3.6.1) Introduction

The stages described here are for Category II products. Having prepared the Technical File as described in 3.5), ensured that a Factory Production Control system is in place according to 3.3) and selected a Notified Body according to 2.8), type approval testing can begin. Prior to this, however, manufacturers may decide to have 'screening' tests performed by a laboratory in Pakistan; this can help in eliminating major non-conformities prior to sending the samples to the Notified Body in Europe.

3.6.2) Screening tests

Although screening tests add time and some cost to the procedure, local testing will be cheaper than Notified Body testing, and will save the time and expense of having to resend sample to the Notified Body for retesting. Experience with the TRTA II programme has shown that gloves and boots made in Pakistan struggle to achieve positive results in all tests when they are first sent to the Notified Body, so screening tests are highly recommended.

Any screening tests should be done by a fully competent, ideally accredited, test laboratory using exactly the same test methods as those used by the Notified Body. As stated above, however, even though tests done in Pakistan can help remove many defects in the products, they cannot be used as the basis for CE marking.

3.6.3) Type-approval testing and certification by the Notified Body

The chosen Notified Body will provide the manufacturer with a quote which will include an amount for testing and, usually, a separate amount for certification. Some Notified Bodies may offer a service for “Preparation of the Technical File” but, as long as the manufacturer has followed the example given in this Guide, this service is not necessary. The quotation should indicate the number of samples which need to be submitted, and the Notified Body should, having assessed the Technical File prior to giving a quote, have considered any variants proposed in the File. Even where variants are grouped, the Notified Body will ask for one or more samples of all sizes, and possibly of all variants, because size and ergonomics need to be tested for all sizes and the Notified Body needs to verify that they really are variants.

Manufacturers must send all test samples requested, because failure to do so will simply lead to unnecessary delays.

The Notified Body will provide a contract to be signed by the manufacturer and will usually request that the entire testing fee be paid in advance, with the certification fee being paid only once testing has been successfully completed. If testing is successful, a draft report will be issued to the manufacturer and, once the manufacturer agrees and the final version of the Technical File is accepted by the Notified Body, the EC type approval certificate will be issued. If some tests are not successfully passed, the manufacturer will be informed and the advice in the following section should then be followed.

3.6.4) Correction of defects

Whether an unsuccessful test result means 'failure' and that the type-approval certificate will not be issued depends on the characteristic(s) involved. Any characteristic which has a required “pass” level, and which is not an optional characteristic, must be satisfied (seam strength of gloves and abrasion resistance of soles, for example). There is no 'acceptable degree of non-conformity' permitted by EU directives, 100 % of requirements that have to be met must be met. Failure of an optional characteristic, or failure to meet Level 1, for protective gloves, of one of the four characteristics shown above, would not prevent a type approval certificate from being issued. On receipt of a failed test report from the Notified Body, therefore, the manufacturer must take action to correct the problems related to fully mandatory requirements, and decide what, if anything, to do about other characteristics.

Manufacturers have to accept that the Notified Body has absolute authority in deciding whether a product meets the requirements or not. With this in mind, there is very little point in the manufacturer trying to persuade the Notified Body to change its mind, and there is even less point in trying to argue that the standard is 'unfair'. It is not advisable for the manufacturer to try to change from one Notified Body to another, in the hope of finding a 'less demanding' one (even if, for other reasons, a manufacturer may change from one body to another if he so chooses). All Notified Bodies are accredited to perform the tests in exactly the same way (within the normal limits of uncertainty of each test) as any other body and, therefore, while one body might give a different level of customer satisfaction from another, the notion of 'demanding' versus 'easy' bodies does not exist in Europe.

If failures are identified by the Notified Body, the manufacturer must simply address them and then resubmit samples to the Notified Body for repeat testing. If the failures are minor, the samples may be resubmitted directly to the Notified Body, while if they are more serious or there are too many of them, it may be worth considering further screening tests first. The Notified Body should only repeat those tests and/or assessments which led to the failure and, therefore, the cost of this should be small. However, manufacturers need to be careful that, when changing the product to address one failure, they do not change it in a way that leads to another problem which did not exist before.

When the Notified Body gives a quotation for retesting, this should include a list of test samples required. In some cases (e.g. failure of seam strength of a glove or failure of azo dye content), the Notified Body might ask only for a sample of the seam or a quantity of the material, rather than a complete product. As for initial sample submission, however, the manufacturer must provide what the Notified Body requests.

3.6.5) Drawing up of the Declaration of Conformity (DOC)

A draft DOC will have been drawn up in the preparation of the Technical File. Once all the documentation required for CE marking (test report(s)and EC type approval certificate) is available, the manufacturer signs and dates the Declaration and includes this in the complete Technical File accepted by the Notified Body. This is a crucial point in the process, because it is the signature which indicates that the manufacturer accepts full responsibility for the safety and conformity of his products.

The manufacturer has to take this responsibility himself because, after the initial type-approval testing, there is no third party involvement in the production process (apart from for Category III products). The manufacturer must, therefore, continue to produce the same products as were subject to type-approval, as described in the following final section.

Because the manufacturer claims conformity on the basis of applying standards, it is difficult for him to accept his responsibility if he does not hold a copy of all the standards which have been applied, even if these have actually been applied by the Notified Body or another third party. He should, therefore, purchase and hold a copy of all standards related to product requirements, but he does not need to hold test method standards.

3.6.6) Continuation of production

In order to maintain conformity, the manufacturer must do the following:

- keep the product and its component parts (including materials) fundamentally unchanged,
- inform the Notified Body of any changes to the product or its component parts which might have an effect on the product's conformity,
- have the type-approval certificate renewed at whatever interval the Notified Body specifies,

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- monitor the European Commission's website to check for changes or updates to the relevant standard(s), and
- maintain the Technical File fully up to date, replacing test reports and/or the type approval certificate and the ISO 9001 certificate if applicable.

The Notified Body might require, in the test report, to be informed of any 'major' changes and does not, therefore, need to know about 'minor' changes. In practice however, from a technical point of view, it is irrelevant whether a change is 'major' or 'minor'; what is important is whether the change has an effect on continued conformity. For example, changing the colour of one minor leather part of a glove may be a minor technical change, but the new part could fail pH, azo dyes or chromium VI content and the resulting product would no longer fulfil all regulatory requirements. If the manufacturer has any doubts about a change, he should consult the Notified Body anyway.

Changes to standards should be checked at least once every five years after the date of publication (all standards are reviewed every five years, whether they are changed or not). Standards may, of course, be amended more frequently than this. If the manufacturer becomes aware of a new version of a standard, he should consult the Notified Body to identify whether any new or repeat testing is required.

Apart from these measures, however, as long as nothing changes, the manufacturer may continue to apply CE marking to his products indefinitely.

Annex 1: EXAMPLE TECHNICAL FILE FOR PROTECTIVE GLOVES

Note that this example is used only to show the principles and layout of a Technical File. It does not correspond to any particular real gloves and it might not be fully complete or internally consistent.

Standards applied EN 420:2003 EN 388:2003	Lovely Gloves Ltd. Pakistan	Technical File Number SG-1, Revision 0 Issue date: 03/10/2013

CE MARKING TECHNICAL DOCUMENTATION

Category II Nitrile coated protective gloves

Council Directive 89/686/EEC

Lovely Gloves Ltd, Sialkot, Pakistan

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Preparation: This Technical File is prepared initially without test reports (in respect of CE marking-related characteristics), Declaration of Conformity or identification of the Notified Body. These are added on receipt of the EC type-approval certificate from the Notified Body. For re-validation of the type-approval certificate, the full Technical File is submitted to the Notified Body.

1) Document introduction

This Technical File describes the nitrile coated protective gloves and demonstrates how these gloves meet the requirements of the EU Personal Protective Equipment Directive 89/686/EEC. This document has been produced according to the requirements of Annex III of the directive.

This Technical File identifies the products and their materials, the manufacturing and production control method, the Basic Health and Safety Requirements of Annex II of the directive, and the harmonized European Standards applied to demonstrate conformity with these Requirements. The European Standards applied demonstrate that the gloves submitted for EC type approval meet the provisions of the directive, while the production control method ensures that all production continues to meet these provisions.

This Technical File also covers the satisfaction of EU requirements on regulated dangerous substances.

2) Product description

Product name: Nitrile coated protective gloves

Sizes: XXS, XS, S, M, L, XL, XXL and XXXL (sizes 6 13)

Colour: Yellow, blue

Category: PPE Category II mechanical protection

3) Product article numbers

Article number: NT-YL, NT-BL

Standards: EN 420:2003, EN 388:2003

4) Description of materials and components in the product

Primary materials: Natural cotton with nitrile dipping

Components: Cotton/polyester thread for stitching

Regulated substances: All materials and components are tested and certified to contain no regulated dangerous substances above limits prescribed by EU regulations (see certificates under Section 10 below)

5) Manufacturing method

The manufacturing method of these gloves comprises the following main stages:

i) Purchase of raw materials

All purchase orders for materials and components are placed according to our own technical specifications.

ii) Material/component reception inspection

All (100 %) deliveries are inspected and tested according to the following characteristics:

a) material/component quantity,

b) material/component quality (visual inspection),

c) material hardness/softness (where applicable),

d) material colour and thickness,

e) material gauge/weight, and

f) material delivery report/certificate.

Accepted materials/components are delivered to storage; rejected materials/components are returned to the supplier, giving the reasons for rejection.

iii) Knitting

After verification of material from the quality control department, the material is forwarded to the knitting department through an internal purchase order, in order to knit the fabric.

iv) Calendaring

After knitting the fabric according to customer requirements and receiving a QC Pass from the quality control department, the said fabric is calendared to increase the tubular width of the fabric according to pattern and also to improve the smoothness of the fabric which helps during the printing process.

v) Printing

Calendared fabric, after getting a pass from the quality control department, is moved to the printing department, where printing is made through wooden block/patterns that helps the operator to trace the pattern during the stitching process.

vi) Cutting

After printing, the operator cuts the fabric and makes bundles of one dozen and then all components are quality checked for size.

vii) Stitching

After cutting, the materials and components are stitched, by machine and by hand, according to the master sample and size. Cotton/polyester thread is used, of colour corresponding to the overall model colour.

viii) Wrist attachment

The produced gloves are forwarded to the wristing department for attaching the wrist to the liner.

ix) Gloves reversing

Gloves are reversed after stitching (liner stitch + wrist attachment) in order to press them.

x) Dipping

The gloves are sent to the dipping department for coating the chemical material on to the gloves according to the customer requirements.

xi) Pressing

Gloves are pressed on electrical moulds in order to make them smooth and sorting of fresh and B-Grade stock, and then fresh stock is packed in polythene bags.

xii) Final inspection

After pressing, all gloves are inspected at AQL 2.5 by Quality Control staff, to ensure that the gloves are properly manufactured, against the following criteria:

a) finish,

b) stitching quality,

c) size according to master sample, and

d) information label/logo/user instruction manual.

xiii) Packing

Following finished product inspection, products are sent for packing in pre-printed packaging. The product label is checked against information on packaging, and packed products are then stored by order, size and colour, ready for distribution/shipping.

6) User information

The following user instructions are to be included in the packaging of each pair of gloves.

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USER INFORMATION

Product Reference: Five fingered Machine knitted wrist cotton gloves with yellow [blue] nitrile coating NT-YL [NT-BL]

Manufacturers address: Lovely Gloves Limited, High Road, Sialkot, Pakistan

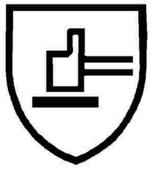
Certification Body: Gloves Certification Ltd., Industrial Estate 1, Hereford, UK (Notified Body: 0123)

These products are classed as Personnel Protective Equipment (PPE) by the European PPE Directive (89/686/EEC as amended) and have been shown to comply with this Directive through the harmonized European Standards EN388:2003 and EN 420:2003

CAREFULLY READ THESE INSTRUCTIONS BEFORE USING THIS PRODUCT

This product is designed to minimize the risk of/provide protection against general mechanical risk. However always remember that no item of PPE can provide full protection and care must always be taken while carrying out the risk-related activity.

PERFORMANCE AND LIMITATIONS OF USE: These products have been tested in accordance with EN420:2003+A1:2009 and EN 388:2003 and achieved following performance levels:



Property	Performance level achieved	Maximum performance level
Abrasion resistance	3	4
Blade cut resistance	1	5
Tear resistance	1	4
Puncture resistance	1	4

Area of use:

General purpose glove for light-weight industrial use.

Use and maintenance:

- The user should select appropriate gloves depending on use. The manufacturer is not responsible for incorrect selection.
- Wear gloves with dry and clean hands.
- Make sure that the inside of the gloves is dry when reusing.
- Make sure that there are no holes in the gloves when reusing.
- Clean the gloves before pulling off.
- Laundering or dry cleaning may decrease the levels of performance.

Storage:

Store gloves in their own package and keep them at room temperature.

Sizes available: 06 to 11 (XXS to XL)

7) Quality management system

Lovely Gloves Ltd., Pakistan, operates a Quality Manager System according to ISO 9001 but without certification. In summary, the Quality Plan comprises the following:

Item	Activity/process	Procedure No.	Inspection point No.	Department responsible
1	Material/component purchase	SGI/QSP/02/01		Purchasing Department
2	Material reception inspection	SGI/QSP/02/11	SGI/QSP/02/11	Quality Control Department
3	Knitting	SGI/QSP/02/06		Production Department
4	Calendaring	SGI/QSP/02/06		Production Department
5	Printing	SGI/QSP/02/06		Production Department
6	Cutting	SGI/QSP/02/10		Production Department
7	Stitching and size	SGI/QSP/02/10		Production Department
8	Wrist attachment	SGI/QSP/02/10		Production Department
9	Reversing	SGI/QSP/02/10		Production Department
10	In-process inspection	SGI/QSP/02/11	SGI/QSP/02/11	Quality Control Department
11	Final inspection	SGI/QSP/02/11	SGI/QSP/02/11	Quality Control Department
12	Packing	SGI/QSP/02/10		Packing Department
13	Storage	SGI/QSP/02/10		Storage Supervisor
14	Distribution/shipping	SGI/QSP/02/10		Export Department

8) Compliance with the PPE Directive 89/686/EEC

The products covered by this Technical File address the following clauses in Annex II of Directive 89/686/EEC:

1.1 Design principles

1.2 Innocuousness of PPE

1.3 Comfort and efficiency

1.4 Information supplied by the manufacturer

2.2 Parts of the body enclosed use of absorptive materials

2.12 PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety

3.1 Protection against mechanical impact

3.3 Protection against physical injury (abrasion, perforation, cuts and bites) bite protection is not relevant

Compliance with these provisions is demonstrated by applying European Standards EN 420:2003+A1:2009 and EN 388:2003 with EC type-examination performed by Gloves Certification Limited, UK.

9) Product marking

Lovely Gloves Ltd. nitrile coated protective gloves are marked, on the label, with:

I) the CE marking symbol, indicating conformity with the PPE Directive 89/686/EEC,

ii) identification of the manufacturer when sold in Lovely Gloves' name (when distributed by another company, the name or trade mark of the other company may appear in place of Lovely Gloves),

iii) the glove designation (NT-YL [NT-BL]),

iv) the size of the gloves according to EN 420:2003+A1:2009,

v) the mechanical risks pictogram followed by EN 388:2003, and

vi) the performance information, as classifications, in the order: abrasion, blade cutting, tear resistance and puncture resistance (3 1 1 1).

The following shows the label attached to each glove.

CE	Lovely Gloves NT-YL Size 7, XS	EN 388:2003 3 1 1 1

The packaging shall be marked with the above information, together with:

- the product name,
- the category of the gloves (II),
- the “See User Information” symbol, and
- the dexterity.

The following shows the information printed on the packaging:

CE	Lovely Gloves Size 7, XS
Category II, 3111 EN338:2003 Dexterity 5	Nitrile coated protective gloves

10) Test reports

Full test report inserted here.

11) Product certificate

EC type-approval certificate inserted here.

Declaration of Conformity

The manufacturer covered by this Declaration, Lovely Gloves Ltd., Sialkot, Pakistan

Declares that the: Nitrile coated protective gloves, in sizes XXS, XS, S, M, L, XL, XXL and XXXL, manufactured from natural cotton, stitched with cotton/polyester thread

are in conformity with the provisions of Council Directive 89/686/EEC, through conformity with the standards EN 420:2003+A1:2009 and EN 388:2003

and are identical to the gloves which are the subject of the EC type-certificate No. 6543 Issue 1

issued by: Gloves Certification Limited, UK, notification reference number 0123.

The technical documentation required to demonstrate that the products meet the requirements of the Personal Protective Equipment Directive 89/686/EEC has been compiled and is available for inspection by the relevant enforcement authorities.

Signed:..... Authority: .....QUALITY MANAGER.....

Signed in: .....Sialkot..... Date: .....03/02/2015.....

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Annex 2: EXAMPLE TECHNICAL FILE FOR MOTORCYCLE BOOTS

Note that this example is used only to show the principles and layout of a Technical File. It does not correspond to any particular real boots and it might not be fully complete or internally consistent. This file has been prepared before test results have been received, so the notion of information in green can be seen.

Standards applied EN 13634:2010	Solid Boots Limited Pakistan	Technical File Number SB-1, Revision 0 Issue date: 24/09/2013

CE MARKING TECHNICAL DOCUMENTATION

Category II Motorcycle racing boots

European Council Directive 89/686/EEC

Solid Boots Limited, High Road, Sialkot, Pakistan

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Preparation: This Technical File is prepared initially without test reports (in respect of CE marking-related characteristics), Declaration of Conformity or identification of the Notified Body. These are added on receipt of the EC type-approval certificate from the Notified Body. For re-validation of the type-approval certificate, the full Technical File is submitted to the Notified Body.

1) Document introduction

This Technical File describes the Solid Boot Limited Category II boots for motorcyclists and demonstrates how these boots meet the requirements of the EU Personal Protective Equipment Directive 89/686/EEC. This document has been produced according to the requirements of Annex III of the directive.

This Technical File identifies the products and their materials, the manufacturing and production control method, the Basic Health and Safety Requirements of Annex II of the directive, and the harmonized European Standard applied to demonstrate conformity with these Requirements. The European Standard applied demonstrates that the boots submitted for EC type approval meet the provisions of the directive, while the production control method ensures that all production continues to meet these provisions.

This Technical File also covers the satisfaction of EU requirements on regulated dangerous substances.

2) Product description

	Product name: SB-04011962 MOTORCYCLE BOOT Sizes: 38-48 EU Colour: Black Category: PPE Category II mechanical protection
	Product name: SB-28061959 MOTORCYCLE BOOT Sizes: 38-48 EU Colour: Black Category: PPE Category II mechanical protection
	Product name: SB-04041995 MOTORCYCLE BOOT Sizes: 38-48 EU Colour: Black Category: PPE Category II mechanical protection

All boots are variants based on the same sole and sole-upper connection. All bonded leather, foam and lining material is the same, in respect of material properties, pH and dangerous substances

3) Description of materials and components in the product

Primary materials: Bonded leather, 100 % Polyester lining, Reflector fabric, TPU protectors, 100 % Rubber sole, Foam sheet, adhesive

Components: TPU protectors, Closures, Laces, Stiffener

Regulated substances: All materials and components are tested to contain no regulated dangerous substances above limits prescribed in the EU REACH Directive (see test report in Section 9 below)

See Annex A for a detailed listing of all materials and components.4) Manufacturing method

4) Manufacturing method

The manufacturing method of these boots comprises the following main stages:

i) Purchase of raw materials

All purchase orders for materials and components are placed according to our own technical specifications.

ii) Material/component reception inspection

All (100 %) deliveries are inspected and tested according to the following characteristics:

a) material/component quantity,

b) material/component quality (visual inspection),

c) material hardness/softness (where applicable),

d) material colour and thickness,

e) material gauge/weight, and

f) material delivery report/certificate.

Accepted materials/components are delivered to storage; rejected materials/components are returned to the supplier, giving the reasons for rejection.

iii) Cutting

Bonded leather, nylon fabric, reflector and other materials are cut to pattern by press, and trimmed using scissors. After cutting, all components are quality checked for size.

iv) Stitching

After cutting, the materials and components are stitched, by machine and by hand, according to the master sample and size. Polyester thread is used, of colour corresponding to the overall model colour.

v) Final 100 % inspection

After stitching, all (100 %) boots are inspected by Quality Control staff, to ensure that they are properly manufactured, against the following criteria:

a) finish,

b) stitching quality,

c) size according to master sample, and

d) information label/logo.

vi) Packing

Following finished product inspection, products are sent for packing in pre-printed packaging. The product label is checked against information on packaging, and packed products are then stored by order, size and colour, ready for distribution/shipping.

5) User information

Product: Solid Bonded Leather motorcycle boots

Manufacturer: Solid Boots Limited, Pakistan

Solid Boots Ltd. bonded leather motorcycle boots are Personal Protective Equipment products of Category II according to EU Directive 89/686/EEC and have been shown to comply with the requirements of this directive through EU type-approval certification by Notified Body WXYZ, according to the requirements of harmonized European Standard EN13634:2010.

The following user instructions are to be included in the packaging of each pair of gloves.

CAREFULLY READ THESE INSTRUCTIONS BEFORE USING THIS PRODUCT

Solid Boots Ltd. bonded leather motorcycle boots are designed to provide reasonable protection to feet against mechanical and impact risks resulting from normal riding and falls from a motorcycle. Risks may arise from material thrown up from another vehicle, impact with roadside items or another machine, or from impact with the ground.

However, no item of personal protective equipment can provide full protection against all possible risks, and care must always be taken while carrying out the risk-related activity. The protection offered by these boots is limited to their performance in type-tests.

PERFORMANCE AND LIMITATIONS OF USE: Solid Boots Ltd. bonded leather motorcycle boots have been tested according to the provisions of EN 13634:2010 and have achieved the following performance levels:

Uppers	
- Abrasion resistance	Level
- Impact cut resistance	Level
Linings	
- Tear strength	Pass
- Abrasion resistance	Pass
Insole and in sock	
- Abrasion resistance	Pass
Outsoles	
- Abrasion resistance	Pass
- Hydrolysis	Pass
- Interlayer bond strength	Pass (or bond strength in N/mm)
Ergonomic requirements	Pass all
Transverse rigidity	Level
Shin and ankle impact protection	Pass (or force in N)
Resistance to water penetration	Pass
Resistance to fuel oil of the outsole	Pass
Slip resistance of outsole	Performance code
Permeable uppers	Pass

No boots can protect against all possible injuries derived from motorcycle accidents. These boots do NOT protect against:

- severe bending, crushing and torque forces, particularly those to the foot which can occur when the leg is trapped between the motorcycle and the ground or another vehicle during an accident; or
- high energy impact to the foot and severe bending forces or twisting.

Solid Boots Ltd. warrants this product under normal usage against defects in workmanship and materials to the original purchaser for one year from purchase date.

1. This warranty does not cover any incidental or consequential damages, such as personal injury or any other losses due to accident, neglect, misuse, abuse, modification, normal wear and tear, orimproper care and cleaning.
2. This warranty does not cover improper fit. It is the responsibility of the consumer to ensure proper fit at the time of purchase.
3. This warranty does not cover the use of these boots in competitions.
4. There are no other warranties implied except this express limited warranty.

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When returning a defective product for warranty purposes, the claimant must provide proof of purchase and a written description of damage.

The manufacturer does not accept any responsibility in case of improper use or the violation of traffic regulations. If the boots are used for any inappropriate purpose, and cause any accident, injury and loss of life, the manufacturer will refuse to take any responsibility.

Solid Boots Ltd. bonded leather motorcycle boots are not designed to provide protection when handling chemicals, or against hot or cold objects. They are not, either, designed to give protection against electric shock or the build-up of static electricity. Consequently they must not be used for these purposes.

European Standard EN 13634:2010 includes two performance levels in terms of the protection afforded. The degree of risk or hazard that a motorcyclist will face is closely linked to the type of riding and the nature of the accident. In standard EN 13634:2010, 'Level 1' performance is deemed as the minimum level required in order for the footwear to provide useful protection in an accident, and offers footwear with an optimum comfort level to suit all riding types. Where riders feel that their riding style or sport exposes them to an increased accident risk, 'Level 2' has been provided which offers increased performance. However, it is likely that this additional level of protection has an increased penalty for the weight and comfort, so may not be acceptable to all riders.

FITTING AND SIZING: Solid Boots Ltd. leather motorcycle boots should only be used in the correct size. Boots which are either too loose or too tight may restrict movement, will not provide the optimum level of protection, may be damaged, and may lead to loss of control of the motorcycle. The size of these boot is marked on the boot and on the packaging and they are available in sizes 38-48 EU.

COMPATIBILITY: To optimize protection, it may in some cases be necessary to use these protective boots for motorcycle riders with other suitable protective equipment (e.g. additional boot liners). In such cases, consult the supplier of these other products to verify their compatibility with these boots and their suitability for your application.

DAMAGE: Boots which are worn, ripped or otherwise damaged will not provide the same levels of protection as the boots when new. Boots should be regularly inspected, and damaged boots should always be replaced.

CARE INSTRUCTIONS, STORAGE AND MAINTENANCE:

CLEANING AND CARE: Motorcycle boots should be cleaned following the instructions written on the label stitched inside the boot:

- after each use, use a soft brush or damp cloth to wipe off dust, mud and oil. Use a sponge with soapsuds to move stubborn dirt,
- do not use solvents, chemical cleaning products or hard brushes, as they may damage leather and plastic parts,
- do not use washing machine or pressure-cleaning machine to clean boots, as high temperature and high pressure may cause damage,
- dry boots in a well-ventilated place. Avoid sunlight. Do not use a radiator or a heater, and
- to keep leather soft, apply neutral leather cream regularly.

STORAGE AND TRANSPORT: When not in use, store the boots in a well-ventilated area away from extremes of temperature. If the boots are wet or dirty, they should be wiped with the dry cloth and allowed to dry naturally before storage. Never place heavy items on top of the boots. If possible, avoid excessive folding and preferably store them hanging vertically.

REPAIR: Do not repair. If protective boots for motorcycle riders are damaged, they will NOT provide the desired level of protection, and they are not designed to be repaired. Never use damaged boots, and damaged boots

should be replaced immediately.

LIFETIME AND CARE INSTRUCTIONS: Under normal conditions, and without damage, these boots should continue to provide protection for up to 3 years.

DISPOSAL: In general, boots are classified as household consumables. They must be placed in a dedicated space according to local regulations."

6) Quality management system

Solid Boots Ltd. Pakistan, operates a Quality Manager System according to ISO 9001, certified by Quality Certifications Ltd., Berlin. In summary, the Quality Plan comprises the following:

Item	Activity/process	Procedure No.	Inspection point No.	Person responsible
1	Material/component purchase	QMP-05		Purchasing Department
2	Material reception inspection	QMP-06	QMI-06	Quality Control Department
3	Cutting	QMP-07		Production Departm ent
4	In-process inspection	QMP-08	QMI-08	Quality Control Department
5	Stitching and size	QMP-09		Production Department
6	Final inspection	QMP-10	QMI-10	Quality Control Department
7	Packing	QMP-11		Packing Department
8	Storage	QMP-12		Storage Supervis or
9	Distribution/shipping	QMP-13		Export Department

The ISO 9001:2008 certificate from Quality Certifications Ltd., Berlin, is inserted here.

7) Compliance with the PPE Directive 89/686/EEC

The products covered by this Technical File address the following clauses in Annex II of Directive 89/686/EEC:

1.1 Design principles

1.2 Innocuousness of PPE

1.3 Comfort and efficiency

1.4 Information supplied by the manufacturer

2.2 Parts of the body enclosed use of absorptive materials

2.12 PPE bearing one or more identification or recognition marks directly or indirectly relating to health and safety declaration of no dangerous substances provided and inclusion of mechanical protection symbols

3.1 Protection against mechanical impact

3.3 Protection against physical injury (abrasion, perforation, cuts and bites) bite protection does not apply

Compliance with these provisions is demonstrated by applying harmonized European Standard EN 13634:2010.with EC type-examination performed by Notified Body WXYZ, 3210.

8) Product marking

Solid Boots Ltd. bonded leather motorcycle boots are marked, on the label, with:

I) the CE marking symbol, indicating conformity with the PPE Directive 89/686/EEC,

ii) identification of the manufacturer,

iii) manufacturer's type designation,

iv) the size of the boots according to EN 13634:2010,

v) year of manufacture and at least the month,

vi) Category II,

vii) the standard number EN 13634:2010,

viii) the motorcycle use symbol and the characteristics in the order of Abrasion resistance, Impact cut resistance, and Transverse rigidity (indications Level X, Level Y and Level Z),

ix) the symbols: IPA for boots providing impact resistance, IPS for boots meeting the shin protection requirements, WR for boots meeting water protection requirements, FO for boots resistant to fuel oil, SRA, SRB or SRC for slip resistant boots and B for boots with water vapour permeable uppers,

x) The care symbols:

The symbols shall be shown separately from the CE marking information, however. The following shows the label attached to each boot.

CE	Solid Boots Ltd. Type 28061959 Size 42
2013/01 Category II	EN 13634:2010 Level X Y Z IPA, IPS,WR, FO, SRA, B

The packaging shall also be marked with the above information

9) Test reports

This section will contain all test reports as received from the Notified Body.

10) Product type approval certificate

This section will include the EC type-approval certificate issued by the Notified Body.

Declaration of Conformity

The manufacturer covered by this Declaration, Solid Boots Ltd., Sialkot, Pakistan

Declares that the: Solid Boots Ltd. bonded leather motorcycle boots, in sizes EU 38-48,

are in conformity with the provisions of Council Directive 89/686/EEC, through conformity with the standard EN 13634:2010 and are identical to the boots which are the subject of the EC type certificate No. WXYZ/PPE/3210 issued by: Notified Body WXYZ, notification reference number 3210.

The technical documentation required to demonstrate that the products meet the requirements of the Personal Protective Equipment Directive 89/686/EEC has been compiled and is available for inspection by the relevant enforcement authorities.

Signed: .....

Authority:.....Quality Manager.....

Signed in: .....

Date: .....

Annex A) Lists of materials and components

Model SB-04011962

	COMPONENTS	COLOUR	REFERENCE	MATERIAL	SURFACE MASS	GAUGE	THICKNESS	SUPPLIER(S)
Boot upper	Main material	Black	BL 19080	Bonded leather		1.83	1.8 -2.5mm	ATS SYNTHETIC (PVT) LTD., Lahore.
	Calf area piping	Black		PU	4.2 g/m^2			ATS SYNTHETIC (PVT) LTD., Lahore.
	TPU			Hard plastic				China Enlighten Trading (Hong Kong) Co. Ltd.
	Adjustable closure			Velcro				NEXO CHINA Shanghai
	Polyester lining			Polyester fabric + foam 5 mm	3.6 g/m^2			Kolon Fashion Material, Inc, Korea
	Padding			PVC plastic + foam in ankle area		1.2	2 mm	BNT, Lahore
	Toe slider							Ideal Industries, Faisalabad
	Toe puff + foam + cotton fabric intoearea							BNT, Lahore
Outsole	Sole	Black	M2011	Rubber				China Enlighten Trading (Hong Kong) Co. Ltd.
Inside sole	Insole			PPE plastic				BNT, Lahore
	Insock			100 % polyester				BNT, Lahore

Model SB-28061959

	COMPONENTS	COLOUR	REFERENCE	MATERIAL	SURFACE MASS	GAUGE	THICKNESS	SUPPLIER(S)
Boot upper	Main material	Black	BL 19080	Bonded leather		1.83	1.8 -2.5mm	ATS SYNTHETIC (PVT) LTD., Lahore.
	Stretch panel	Black		PU at shin arch area				ATS SYNTHETIC (PVT) LTD., Lahore.
	Reflector							NEXO CHINA / BENAV SPORTS, Shanghai
	TPU			Hard plastic				China Enlighten Trading (Hong Kong) Co. Ltd.
	Adjustable closure			Velcro				NEXO CHINA / BENAV SPORTS, ShanghaiChina
	Polyester lining			Polyester fabric + high pora + foam 5 mm	3.6 g/m^2			Kolon Fashion Material, Inc., Korea
	Padding			PVC plastic + Eva foam in ankle area		1.2	2 mm	BNT, Lahore
	Stiffener heel back counter							BNT, Lahore
	Toe puff + EVA foam + cotton fabric in toe area							BNT, Lahore
Outsole	Sole	Black	M2011	Rubber				Ideal Industries, Faisalabad
Inside sole	Insole			PPE plastic				BNT, BhamaChowk, Bund Road, Lahore, PAKISTAN
	Insock			100 % polyester				BNT, BhamaChowk, Bund Road, Lahore, PAKISTAN

Model SB-04041995

	COMPONENTS	COLOUR	REFERENCE	MATERIAL	SURFACE MASS	GAUGE	THICKNESS	SUPPLIER(S)
Boot upper	Main material	Black	BL 19080	Bonded leather		1.83	1.8 -2.5mm	ATS SYNTHETIC (PVT) LTD., Lahore.
	Other material	Black		Matt nylon with leather backing				ATS SYNTHETIC (PVT) LTD., Lahore.
	Reflector							NEXO CHINA / BENAV SPORTS, Shanghai
	Laces			Polyester				NEXO CHINA / BENAV SPORTS, Shanghai
	Adjustable closures			Velcro				NEXO CHINA / BENAV SPORTS, Shanghai
	Polyester lining			Polyester fabric + high pora + foam 5 mm	3.6 g/m^2			Kolon Fashion Material, Inc.,Korea
	Padding			PVC plastic + Eva foam in ankle area		1.2	2 mm	BNT, Lahore
	Stiffener heel back counter							BNT, Lahore
	Toe puff + EVA foam + cotton fabric in toe area							BNT, Lahore
Outsole	Sole	Black	M2011	Rubber				Ideal Industries, Faisalabad
Inside sole	Insole			Plastic				BNT, Lahore
	Insock			100 % polyester				BNT, Lahore